DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

HFI-35

m3761n

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
FAX: (781) 279-1742

WARNING LETTER
NWE-29-00W

VIA FEDERAL EXPRESS

May 17, 2000

Philip Hamrock
President
Aplicare, Inc.
50 East Industrial Road
Branford, CT 06405

Dear Mr. Hamrock:

During an inspection of your drug manufacturing facility, Aplicare, Inc., 50 East Industrial Road, Branford, CT 06405, on April 5 through 14, 2000 our Investigator found significant deviations from the Good Manufacturing Practices for Finished Pharmaceuticals (Title 21 Code of Federal Regulations, Parts 210 and 211). Your firm manufactures antiseptic products, including povidone iodine preps, which are considered to be drugs. Such deviations cause drugs manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food Drug and Cosmetic Act (the Act). The violations observed during our inspection include, but are not limited to, the following:

1. Failure to have and follow written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. For example, your firm has not completed validation for the re-sterilization of your antiseptic products. Since January 1998, on at least four occasions, you resterilized the batch when positive sterility results were obtained. There was no documentation available to indicate that these re-sterilization procedures have been validated to assure that this step did not compromise the product, i.e., package integrity. Also, your validation does not include any rationale for the use [redacted] as an appropriate indicator organism (i.e., most resistant to iodine). It was also noted that your bioburden validation was not representative of your manufacturing microbial load.

Also, there are no written procedures for the adjustment of bulk iodine solutions nor are there any written procedures for the investigations of results that are out of specification.

2. Failure to have written procedures for the reconciliation of labels issued to production.

3. Failure to have batch production records that include complete information relating to the production of each batch. For example, during the inspection on 4/6/2000, it was noted that the "Aplicare Sterilization Checklist – Sterilizer #2" was signed off as "performed by" prior to completion of the loading process.

4. Failure to have an appropriate written procedure that would prevent objectionable microorganisms in your drug products. For example, your environmental control procedure does not include any action to be taken when the biological limits are exceeded. On 3/24/00, the settling plates for machine #5 exceeded the microbial limits and no specific action was taken.

You should take prompt action to correct all of the violations at your firm. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions may include seizure and or injunction under the Federal Food, Drug, and Cosmetic Act.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the above violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

We acknowledge your letter dated April 25, 2000 which was in response to the FDA 483 that was issued to your firm at the close of our inspection. We understand from your response that you are in the process of making corrections. Therefore, in your response to this Warning Letter, please advise us of your current status and the supporting documentation you have to date with respect to the above serious deficiencies at your facility.

The deficiencies identified in this letter are not intended to be an all-inclusive list of the deficiencies at your facility. As President, it is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 279-1675, Extension 113.

Sincerely,

Gail T. Costello
District Director
New England District Office

cc:
Bruce H. Wilson
Vice President
Aplicare, Inc.
50 E Industrial Road
Branford, CT 06405